Exhibit B

Peggy C. Pence, PhD, RAC, FRAPS

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PROFESSIONAL SUMMARY

Dr. Pence offers over 43 years of experience in the research and development of traditional pharmaceutical and biotechnology-derived therapeutic products and medical devices, including in vitro diagnostics. Dr. Pence began her career at Eli Lilly and Company in 1970 in basic immunology research and later transitioned to clinical development and regulatory affairs. She subsequently held key project and clinical management positions at several emerging-growth companies, namely the U.S. start-up of Serono Laboratories, Triton Biosciences (acquired by Berlex Laboratories, Inc.), and Amgen, Inc. In 1992, Dr. Pence founded a consulting firm that was incorporated in 1995 as Symbion Research International, a full-service contract research organization. She has been President and Chief Executive Officer since that time.

Over the course of her longstanding career, Dr. Pence has worked with over 80 companies and over 90 drugs, biologics, and medical devices spanning multiple therapeutic areas. She has broad experience in regulatory affairs and strategic planning, nonclinical testing, and all phases of clinical trials. Dr. Pence has enjoyed success in leading development programs for a number of novel products and has designed and managed numerous clinical studies, from first-in-man to pivotal studies to support marketing applications. She established, staffed, and directed the Clinical Quality Assurance and Document Control department at a leading biotechnology company, Amgen, Inc. She has directed collaborative clinical programs with foreign affiliates to reduce overall clinical development time and costs and enhance quality and usability of data globally for marketing applications. Dr. Pence has served as the U.S. Agent or authorized representative for FDA (Food and Drug Administration) matters for medical device, pharmaceutical, and biopharmaceutical companies. She has prepared numerous regulatory submissions and consulted with the FDA concerning INDs, NDAs, BLAs, IDEs, 510(k)s, and PMAs. She has guided and coordinated product development activities from process development through marketing plans. Therapeutic areas of experience include neurology, neuropsychology, oncology, hematology, infectious disease, rheumatology, nephrology, respiratory disorders, women's health, metabolic and growth disorders, gastroenterology, burns, wound healing, and ophthalmology.

Among her accomplishments, Dr. Pence has consulted for a multinational pharmaceutical company to develop strategy and implement a global clinical data management system and also for a leading software company to develop information management solutions for the pharmaceutical and biotechnology industries. Dr. Pence has been instrumental in assisting a number of companies (both emerging-growth companies and established industry leaders) to evaluate current operations and implement new processes and procedures to achieve greater efficiency and ensure compliance with current regulations.

Dr. Pence earned her undergraduate degree in Microbiology from Louisiana Tech and her PhD in Toxicology from Indiana University. She is an active industry speaker and educator and has developed and taught two graduate-level courses for the California State University system: "Clinical Trials and Quality Assurance" and "Clinical Trials Project Management: Managing Clinical Trials." Dr. Pence founded and chaired the Drug Information Association (DIA) Biotechnology Subgroup and chaired 10 consecutive DIA workshops on biotechnology from 1991 through 2001. Dr. Pence holds the U.S. Regulatory Affairs Certification (RAC) designation and has served on the Regulatory Training Course Faculty, DIA, and as an instructor for the Orange Country Regulatory Affairs Discussion Group (OCRA) for candidates for Regulatory Affairs Certification. Dr. Pence is a RAPS (Regulatory Affairs Professionals Society) Fellow (FRAPS), a peer-reviewed credential for which she was selected based on her experience, contributions, and leadership in the regulatory profession. She has served on the Board of Directors or Advisory Board for multiple organizations.

PROFESSIONAL EXPERIENCE

Founder, President and Chief Executive Officer | Symbion Research International, Inc.
Newbury Park, California | 1995 - Present
Newport Beach, California | 2015 – Present

- Responsible for establishing and maintaining corporate culture, ethical standards, and vision.
- Determine corporate direction and oversee business development.
- Responsible for executive decisions regarding systems implementation, policies, and procedures.
- Provide expert advice to clients regarding regulatory, nonclinical, and clinical development matters and product development strategic planning.
- Serve as regulatory liaison with FDA for client companies.
- Provide expert advice and represent clients for FDA meetings.
- Prepare regulatory submissions or perform critical review to ensure highest quality and successful submissions (e.g., INDs, BLA, IDEs, 510(k)s, PMAs).
- Provide guidance to clients to achieve resolution of non-compliance issues identified during FDA inspection.
- Function as director of product development for virtual companies.
- Directly oversee and participate in clients' pivotal development programs.
- Provide leadership and counsel to Symbion teams assigned to clients' projects.
- Design clinical protocols and programs, proposing innovative methods as appropriate.
- Organize and chair (as appropriate) multi-center Investigators'/Study Coordinators' Meetings.
- Direct the conduct, management, monitoring, data management, analysis, and reporting of clinical trials.
- Evaluate clinical operations of client companies and recommend solutions to increase effectiveness; accordingly, revise and develop Standard Operating Procedures (SOPs).
- Perform quality assurance audits of pivotal clinical trials.
- Conduct training programs in regulatory affairs, Good Clinical Practice, and Good Laboratory Practice.
- Experience with novel therapeutic products, including oncolytic viruses, tissue-engineered products, interferons, monoclonal antibodies, neurotrophic factors, growth factors, peptides, and toxins, as well as new chemical entities; Class I, II, and III medical devices, including in vitro diagnostics; innovative drug delivery systems; and combination products. Clinical indications studied include a variety of cancer types, neurological conditions, pain management, cognitive disorders, diabetes, infectious diseases, including HIV/AIDS and other sexually transmitted diseases, respiratory disorders, gastrointestinal disorders, hepatitis, burns, chronic wounds, and women's health concerns.

President | Product Development Consulting
Newbury Park, California | 1992-1995

- Designed and conducted clinical programs, Phases I to III.
- Established new clinical functions or departments for client companies, including Standard Operating Procedures (SOPs) and systems.
- Evaluated, prepared study reports, and summarized nonclinical and clinical data for NDA submission.
- Evaluated and re-engineered product development processes for implementation of new information technology systems, assessing and planning conversion strategy.
- Served as key member of clients' product development teams, providing expert advice on regulatory and product development matters and strategic planning.
- Prepared regulatory submissions (including clinical protocols and amendments; Investigator's Brochures; initial IND submissions, IND amendments and annual reports; 510(k)s, PMAs; Clinical Study Reports, etc.).

PROFESSIONAL EXPERIENCE (Continued)

- Consulted for a multinational pharmaceutical company to develop strategy and implement a global clinical data management system.
- Provided expert advice to leading software company to develop information management solutions for the pharmaceutical and biotechnology industries.

Amgen, Inc.
Associate Director, Clinical Quality Assurance and Document Control
Manager, Clinical Operations
Manager, Clinical Studies
Thousand Oaks, California | 1988-1992

- Key member of product development teams for consensus interferon and wound-healing growth factors.
- Responsible for preparation or critical review of significant parts of IND submissions.
- Designed and directed clinical programs for consensus interferon and "first-time-in-man" studies of recombinant wound-healing growth factors; consensus interferon program led to licensing approval for treatment of hepatitis C virus infection.
- Awarded management responsibility for ongoing gamma interferon clinical programs.
- Established and staffed clinical quality control and assurance department and functions, developed procedures and systems, and achieved major targeted deadline (for human granulocyte colony stimulating factor [G-CSF] program) within first three months of operation.
- Managed staff responsible for adverse event and concomitant medication coding across all clinical programs worldwide.
- Directed the establishment and functioning of a Clinical Records and Information Center for the storage, organization, protection, and management of clinical trial documents across all clinical programs, including an International Records Library.
- Directed the development of a Case Report Form (CRF) tracking system for all clinical programs, including operating procedures and reporting capabilities.
- Developed comprehensive training curriculum for clinical development staff.
- Responsible for developing and administering annual and five-year research and development plans and budgets.
- Managed staff of over 40 clinical research professionals.
- For all functions, met all targeted deadlines and achieved all departmental and divisional goals at a level of 125% to greater than 150%.

Manager, Therapeutics Projects | Triton Biosciences, Inc.
Alameda, California | 1986-1988

- Project manager accountable for all planning, direction, scheduling, monitoring and control of assigned projects, including recombinant interferon-beta and transforming growth factor, from process development through marketing plans.
- Organized and chaired formal project reviews with co-development company and also internal project team; provided company officers with regular progress reports, through both written documents and oral briefings.
- Prepared master plan for development of a new purification procedure and formulation; assured project control and adherence to the plan to achieve target date for completion.
- Directed compilation from three separate databases and writing of clinical safety assessment for over 500 patients for FDA submission.
- Responsible for evaluation of therapeutic and commercial potential of new chemical entity.
- Key member of strategy-setting team for therapeutic projects.
- Managed major extramural nonclinical research programs; designed and implemented nonclinical toxicology, pharmacology, and efficacy studies.

PROFESSIONAL EXPERIENCE (Continued)

Pharmaceutical Research Manager | Serono Laboratories, Inc.
Randolph, Massachusetts | 1983-1986

- Responsible for the design and execution of nonclinical and clinical development programs in two major product areas: interferon-beta and human growth hormone, both native and recombinant.
- Awarded management responsibility for ongoing trials of bovine thymus peptide product (thymostimulin) in AIDS and AIDS-Related Complex (ARC) patients.
- Took over a mismanaged trial, cleaned it up, and administered FDA's inspections of this trial (including both sponsor and investigator) to successful outcomes.
- Successfully designed and completed Phase I trial, inspected by FDA subsequent to above-noted inspections; inspection completed in approximately two hours, resulting in inspector's pronouncement that this was one of the best audit results he had seen.
- Directed development of collaborative clinical programs with foreign affiliates, notably the United Kingdom, France, Israel, and Italy, to reduce corporate's overall clinical development costs and enhance quality and usability of data globally for marketing applications.
- Designed and implemented four Phase I and II trials, designed and developed Phase III multi-center trials in six indications, including ocular and sexually-transmitted infectious diseases, cervical intraepithelial neoplasia, and growth hormone deficiency. Organized and chaired four multi-center Investigators'/Study Coordinators' Meetings.
- Conceived and successfully proposed Phase III clinical strategy to FDA to reduce the time to NDA submission by approximately one year.
- Recommended a clinical study that led to an application for use patent.
- Implemented a clinical study in collaboration with the National Institutes of Health, which was applauded as a potential landmark study and eventuated letters of commendation both from senior company management and the study investigators.
- Collaborated with overseas manufacturing facilities (Israeli, Italian, and Swiss affiliates) to develop task completion schedules and resolve process development issues; personally arranged characterization and validation studies and coordinated activities with affiliate and contract laboratories to assure timely completion.
- FDA liaison (telephone contacts, formal presentations and meetings).
- Prepared Supplemental New Drug Application and subsequently prepared a presentation of the data therein for FDA Advisory Committee meeting, at FDA's invitation.
- Wrote protocol and SOPs for enzyme-linked immunosorbent assay to detect antibody development in patients treated with interferon-beta.
- Coordinated validation of an antibody assay (for human growth hormone patients) by diagnostics affiliate to effect a 50% savings in assay costs compared to extramural laboratory charges.
- Prepared summary of all non-U.S. safety data (interferon-beta) for submission to regulatory agencies in support of marketing applications; recognized by corporate and affiliate offices for value of contribution.
- Directed the activities of four clinical research professionals and two secretaries.

PROFESSIONAL EXPERIENCE (Continued)

Eli Lilly and Company
Medical Information Administrator, Regulatory Affairs
Indianapolis, Indiana | 1977-1980; 1982-1983
Educational Leave of Absence to Complete Doctoral Research
Indianapolis, Indiana | 1980-1982
Cosmetic Chemist, Research and Development | Elizabeth Arden Division
Indianapolis, Indiana | 1974-1977
Associate Microbiologist, Immunology Research Laboratory
Indianapolis, Indiana | 1970-1974

- Broad exposure to the planning, drug development, and decision-making processes at a leading pharmaceutical corporation.
- Responsible for monitoring Phase III and IV clinical trials for original and supplemental NDA submissions.
- Contributed to preparation of clinical protocols, CRFs, and Investigator's Brochures.
- Collaborated with biostatisticians, computer programmers, and data analysts to establish data entry and verifications systems.
- Prepared a variety of regulatory submissions, including quarterly reports to the newly approved NDA for Humulin®, the first product of recombinant DNA origin to be approved for sale.
- Acquired experience in multiple product categories: antiemetic, narcotic analgesic, anti-inflammatory, and antiparkinsonism drugs.
- Supervised staff of three non-exempt personnel.
- As cosmetic chemist, developed complete line of powder products, troubleshot for pilot plant and production, worked closely with marketing and claims substantiation departments; conducted skin physiology research.
- As associate microbiologist, participated in the design and execution of *in vivo* and *in vitro* experiments to develop a reliable and reproducible screening assay for identifying agents affecting cell-mediated immunity; acquired tissue culture and laboratory animal experience.

EDUCATION

Doctor of Philosophy (PhD), Toxicology, Pharmacology minor
Indiana University (Medical School campus) | Indianapolis, Indiana | 1983
Thesis: Comparative effects of cannabinoids alone and in combination with other centrally acting drugs.
Doctoral research conducted at the Eli Lilly Laboratory for Clinical Research, Indianapolis, Indiana:

- Planned and personally executed all aspects of three clinical pharmacology and toxicology studies, from protocol conception to subject selection to Clinical Study Report.
- Synthetic cannabinoid Cesamet® studied in two of these trials approved by FDA, December 1985; prepared report on drug abuse liability trial results for FDA Drug Abuse Advisory Committee, which report was central to Committee's recommendation (1983) for scheduling under the Controlled Substances Act.

Bachelor of Science (BS), *Magna cum Laude,* Microbiology
Louisiana Polytechnic University (Louisiana Tech) | Ruston, Louisiana | 1969

ACADEMIC HONORS

2008	Selected for Bossier High School Alumni Hall of Fame, Bossier City, Louisiana
1982	Member of Sigma Xi, The Scientific Research Society
1982	Third place, annual Sigma Xi competition for graduate research presentations, Indiana University School of Medicine
1981	Second place, annual Sigma Xi competition for graduate research presentations, Indiana University School of Medicine
Circa 1969	Phi Kappa Phi, Louisiana Polytechnic University
Circa 1969	Beta Beta Beta, Louisiana Polytechnic University
Circa 1968	National Society of Cwens, Louisiana Polytechnic University
1967	Freshman Honor Woman, Louisiana Polytechnic University
1966	Valedictorian, Bossier High School, Bossier City, Louisiana

PROFESSIONAL CERTIFICATION OR DESIGNATION

- U.S. Regulatory Affairs Certification (RAC) | 2006, Recertification 2009, 2012, 2015
- Regulatory Affairs Professionals Society Fellow (FRAPS) | 2009

CURRENT PROFESSIONAL MEMBERSHIPS

- Regulatory Affairs Professionals Society (RAPS)
- Drug Information Association (DIA)
- International Society for Pharmacoepidemiology (ISPE)
- Orange County Regulatory Affairs Discussion Group (OCRA)
- American Urogynecologic Society (AUGS, affiliate member)

PAST PROFESSIONAL MEMBERSHIPS

- The Food & Drug Law Institute (FDLI, corporate membership)
- Southern California Biomedical Council (SoCalBio, corporate membership)
- International Society for Interferon Research
- Project Management Institute
- Northern California Pharmaceutical Discussion Group
- San Francisco Chapter of Association of Biotechnology Companies

SELECTED HONORS AND AWARDS

June 3-4, 2015	Orange County Regulatory Affairs Discussion Group (OCRA) Certificate of Appreciation: Moderator, 18th Annual FDA-OCRA Educational Conference, "The Current Regulatory Landscape: Opportunities and Challenges," Irvine, California
Oct. 6, 2010	OCRA and San Diego Regulatory Affairs Network (SDRAN) Certificate of Appreciation for Presentation: "Getting Your Product to Market in the New Regulatory Environment," San Diego, California
June 17, 2010	OCRA Certificate of Appreciation for Dedication to OCRA, Irvine, California
June 16-17, 2010	OCRA Certificate of Appreciation: Speaker (Moderator), 13th Annual FDA-OCRA Educational Conference, "The Business of Compliance," Irvine, California
Aug. 1, 2009	OCRA Certificate of Appreciation: US RAC Study Group Presenter, Brea, California

SELECTED HONORS AND AWARDS (Continued)

June 9-10, 2009	Orange County Regulatory Affairs Discussion Group (OCRA) Certificate of Appreciation: Award Recipient, OCRA Volunteer Appreciation 2009 for Support of OCRA, Irvine, California
Nov. 19, 2008	OCRA Certificate of Appreciation: Global Clinical Trials, Carlsbad, California
Sept. 6, 2008	OCRA Certificate of Appreciation: US RAC Study Group Presenter, Brea, California

ACADEMIC APPOINTMENTS

2012-2013	Course Developer and Instructor, California State University, Fullerton: Clinical Trials Project Management: Managing Clinical Trials
2011-present	Course Developer and Part-time Faculty, California State University, Channel Islands, MS Biotechnology Program: Clinical Trials and Quality Assurance
Spring 2009	Instructor/Advisor, California State University, Channel Islands, Master of Science in Biotechnology Program Team Projects, Subject: Development Pathway and Issues for Probiotics as Therapeutics

BOARD OF DIRECTORS AND ADVISORY BOARDS

2012 - 2015	The Food and Drug Law Institute (FDLI), *Update* Editorial Advisory Board
2009 - 2013	Biotechnology and Health Programs Advisory Board, California State University, Channel Islands
2009	Clinical Trials Certificate Program Advisory Board, California State University Program for Education and Research in Biotechnology (CSUPERB)
2008 - 2009	Biotechnology Advisory Committee, California State University, Channel Islands
2007 - present	Board of Directors, CompassioNow (formerly CareNow Foundation)
2006 – 2008	Scientific Advisory Board, CytoDyn, Inc.
2003 – 2005	Board of Directors, CytoDyn, Inc.
2003	Board of Directors, VCBio
1989-present	Board of Directors, The Iraida Foundation
1987	First Editorial Advisory Board, *BioPharm Manufacturing*

SELECTED PROFESSIONAL CONTRIBUTIONS

April 30, 2014	"Quality Executive Leadership Series: Quality Leadership Network," Irvine, CA
Sept. 24, 2013	"Quality Executive Leadership Series: FDA and Industry Executives Working Together to Improve Quality," Workshop between U.S. Food and Drug Administration and Industry Executives, Irvine, California
2012 - 2015	Regulatory Affairs Professionals Society (RAPS) Fellows Committee
2009	Southern California Biomedical Council (SCBC) Gold Coast Event Planning Committee
2009	Co-Founder & Meetings Chairperson, Venture Coast Life Science Innovators (VCLSI)
1994 - 1996	Drug Information Association (DIA) Annual Meeting Program Committee, Biotechnology Track
1994	Drug Information Association Regional Steering Committee
1993 - 1995	Drug Information Association Steering Committee of the Americas
1990's	Originator and Chair, Drug Information Association Biotechnology Subgroup

PUBLICATIONS AND RESEARCH PRESENTATIONS

- Robson MC, Phillips LG, Thomason A, Altrock BW, Pence PC, Heggers JP, Johnston AF, McHugh TP, Anthony MS, Robson LE, et al. Recombinant human platelet-derived growth factor-BB for the treatment of chronic pressure ulcers. Ann Plast Surg 1992; 29(3): 193-201.
- Pence, PJC, Lemberger L, Waterhouse GAW, Forney RB. The reactivity of nabilone in the EMIT cannabinoid assay. Presented at the Annual Meeting of the American Academy of Forensic Sciences, Cincinnati, Ohio, February 1983.
- Waterhouse GAW, Pence PJC, Forney RB. Positive urine cannabinoid levels produced in individuals passively exposed to marihuana smoke. Presented at the Annual Meeting of the American Academy of Forensic Sciences, Cincinnati, Ohio, February 1983.
- Lemberger L, Rubin A, Wolen R, DeSante K, Rowe H, Forney R, Pence P. Pharmacokinetics, metabolism and drug-abuse potential of nabilone. Cancer Treatment Reviews 1982; 9 (Supplement B): 17-23.
- Pence PJ, Lemberger L, Cerimele BJ, Forney RB. Comparative response to nabilone and delta-9-tetrahydrocannabinol in the assessment of abuse liability. Presented at the Cannabinoid Meeting, Louisville, Kentucky, August 1982. Presented at the 21st Annual Meeting of the Society of Toxicology, Boston, Massachusetts, February 1982. Published: The Toxicologist 1982 (Abstract).
- Pence PJ, Waterhouse GAW, Lemberger L, Dalton WS, Cerimele BJ, Forney RB. Combined effects of delta-9-tetrahydrocannabinol and cannabichromene in humans. Presented at the 20th Annual Meeting of the Society of Toxicology, San Diego, California, February 1981. Published: The Toxicologist 1981 (Abstract).
- Scheetz ME, Carlson DG, Pence PJ. A sensitive and reproducible assay for the quantitation of the in vitro antibody response to sheep red blood cells and the effect of thymocytes, endotoxin, and phytohemagglutinin on this response. Immunological Communications 1974; 3(2): 175-188.

CONFERENCE CHAIRMANSHIPS OR TRAINING COURSE FACULTY

Aug. 1, 2009	"Medical Device Submissions and Post-Approval Requirements for Medical Devices," Instructor for Orange County Regulatory Affairs Discussion Group (OCRA), US Regulatory Affairs Certification (RAC) Study Group
Sept. 6, 2008	"Device Submissions: PMA, 510(k) (21 CFR Regulations: Devices - 807, 809 & 814)," Instructor for Orange County Regulatory Affairs Discussion Group (OCRA), US Regulatory Affairs Certification (RAC) Study Group
Feb. 12-13, 2001	9th Annual Drug Information Association (DIA) Biotechnology Workshop, Program Co-Chairperson, "Biotechnology: Global Perspectives," Dana Point, California
May 6-7, 2000	8th Annual Drug Information Association (DIA) Biotechnology Workshop, Program Co-Chairperson, "Biotechnology: Global Perspectives," Dana Point, California ○ *Session Chairperson: "Biotechnology in Australia, Europe, and Japan"*
Feb. 1-2, 1999	Drug Information Association (DIA) 7th Annual Biotechnology Workshop, Program Chairperson, "Biotechnology: Product Development for the New Millennium," Dana Point, California
Feb. 5-6, 1998	Drug Information Association (DIA) 6th Annual Biotechnology Workshop, Program Chairperson, "Clinical Trials and Product Development in Biotechnology," Dana Point, California ○ *Session Co-Chairperson: "Getting into the Clinic with Novel Products – DNA Vaccines and Gene Therapy"*

CONFERENCE CHAIRMANSHIPS OR TRAINING COURSE FACULTY (Continued)

Feb. 20-21, 1997	Drug Information Association (DIA) 5th Annual Biotechnology Workshop, Program Chairperson, "Clinical Trials in Biotechnology," Dana Point, California
Jan. 29-30, 1996	Drug Information Association (DIA) 4th Annual Biotechnology Meeting, Program Co-Chairperson, "Regulatory Reform: Its Impact on Clinical Trials and Product Development in Biotechnology," Newport Beach, California ○ *Session Chairperson: "Key Considerations for Regulatory/Clinical Development in the Current Industry Environment"* ○ *Speaker: "Perspectives on the ICH GCP Guideline"*
Jan. 30-31, 1995	Drug Information Association (DIA) 3rd Annual Biotechnology Meeting, Program Co-Chairperson, "Clinical Trials in Biotechnology," Newport Beach, California ○ *Session Chairperson: "Optimizing Data Management for Emerging Biopharmaceutical Companies"*
June 6-7, 1994	Drug Information Association (DIA) Annual Meeting, Biotechnology Track Co-Chairperson
Jan. 30 – Feb. 1, 1994	Drug Information Association (DIA) Annual Symposium on Biologics and Biotechnology, Program Co-Chairperson, "Clinical Trials in Biotechnology: Planning to Prevent the Pitfalls," Newport Beach, California ○ *Session Chairperson: "Tactics for Execution"* ○ *Speaker: "Performing with the Best Actors: Efficiency and Quality"*
May 19-21, 1993	Drug Information Association (DIA) Biotechnology Workshop, Program Chairperson, "Biotechnology: Meeting the Challenges of the 1990s," Boston, Massachusetts ○ *Speaker: "Integrating CAPLAR/CANDA in the Product Development Process"*
Nov. 20-22, 1991	Drug Information Association (DIA) Biotechnology Workshop, Program Chairperson, "Clinical Development of Biotechnology Products," Santa Monica, California ○ *Speaker: "A Comprehensive Approach to Achieving Efficiency and Quality in Clinical Research"*

SPONSORED SYMPOSIA

Oct. 14, 2008	PQC Consulting, Inc., and Symbion Research International, Inc., Co-Sponsored Symposium, "Good Clinical Practice and the Clinical Study Process," Lead Instructor: Peggy Pence, PhD, RAC, Los Angeles, California
Oct. 15, 2003	Symbion Research International, Inc., and Interface International Consultancy, Ltd., Co-Sponsored Symposium: "How to CE Mark a Medical Device," Instructor: Brian James, PhD, FBIRA
Nov. 5, 2002	Symbion Research International, Inc., and Interface International Consultancy, Ltd., Co-Sponsored Symposium: "European Regulations: Medical Devices, Drug-Device Combinations, Orphan Drugs and a Glance into the Future," Instructor: Brian James, PhD, FBIRA, La Jolla, California
Nov. 4, 2002	Symbion Research International, Inc., and Interface International Consultancy, Ltd., Co-Sponsored Symposia: "Drug-Device Combinations: A European Perspective" and "European Regulations: A Glance into the Future," Instructor: Brian James, PhD, FBIRA, Irvine, California

SELECTED PRESENTATIONS

Oct. 1, 2013	"The Importance of Ethics - Postmarketing Challenges," Situation Room Speaker, 2013 RAPS Annual Conference: The Regulatory Convergence, Boston, Massachusetts
Sept. 30, 2013	"The Importance of Ethics - Premarketing Challenges," Situation Room Speaker, 2013 RAPS Annual Conference: The Regulatory Convergence, Boston, Massachusetts
Feb. 26, 2009	"Finding New Medical Therapies: The R&D Process – Discovery Research through Post-Marketing," Guest Lecturer: Biology 601, MS Biotechnology Program, California State University, Channel Islands
Nov. 19, 2008	"The Use of Databases and Electronic Data Capture in Clinical Studies," Speaker (Co-Presenter with Diane Ascoli) and Panel Member: Orange County Regulatory Affairs Discussion Group (OCRA) - San Diego Regulatory Affairs Network (SDRAN) Joint Meeting, "Global Clinical Trials: An Overview and Update," Carlsbad, California
June 10, 2008	"Drugs/Biologics Product Development: Understanding the Complexities, Managing the Risks," Guest Lecturer: Biology 601, MS Biotechnology Program, California State University, Channel Islands
March 27, 2008	"Personalized Medicine, Regulatory Perspective," Speaker and Panel Member, Southern California Biomedical Council Networking Forum: "Personalized Medicine Are We There Yet," Westwood, California
April 24, 2007	"Successful Product Submissions," (Interactive) Audio Conference: Thompson Publishing Group, Co-Presenter with Dr. Kathryn Kimmel
April 17, 2007	"Clinical Data Management: Annual Good Clinical Practices Review," Corporate Program, San Diego, California
Nov. 15, 2006	"Risk-Benefit Analysis in Clinical Development," BioFlorida Annual Conference, Gainesville, Florida
June 6, 2006	"Clinical Data Management: Case Report Form Fundamentals," Corporate Program, San Diego, California
March 2, 2006	"Clinical Data Management: Annual Good Clinical Practice (GCP) Training Workshop," Corporate Program, San Diego, California
Nov. 8, 2005	"Navigating the Drug Development Pipeline from Innovation to Market," Presentation to the Women in Health Administration of Southern California
May 20, 2004	"Integrating Regulatory, Clinical and Marketing Efforts into a Profitable Reimbursement Strategy," Audioconference: FDA News, Co-Presenter with Jennifer Murray and Chris Waugh
Oct. 28, 2003	"Good Clinical Practice (GCP) and Regulatory Training Workshop," Corporate Program, Westlake Village, California
Oct. 20, 2003	"Safari of Life, My Personal Journey: Bench to Business," Presentation to Forum for Women Entrepreneurs, San Diego, California
June 24, 2003	"Good Clinical Practice (GCP) and Regulatory Training Workshop," Corporate Program, Westlake Village, California
Dec. 1-3, 1993	Drug Information Association (DIA) Pharmaceutical Document Management, Program Speaker, San Francisco, California
Sept. 1, 1993	"Good Clinical Practices and Effective Study Monitoring Workshop," Corporate Program, San Diego, California
Jan. 14, 1993	"Preparing for CAPLAR/CANDA," Sun Microsystems Inc. Seminar, San Francisco, California
Sept. 23, 1992	"The Oracle Biotechnology Seminar: Flexible Information Management Within A Regulated Industry," An Executive Seminar with Dr. Peggy Pence, Oracle Corporation, Santa Clara, California
Feb. 1983	Review of the Pharmacology of Cannabinoids. Presented as participant in panel discussion of Analysis, Pharmacokinetics, and Pharmacology of Delta-9-THC, Annual Meeting of the American Academy of Forensic Sciences, Cincinnati, Ohio

SELECTED CONTINUING EDUCATION

Feb. 22, 2016	"Medical Device Adverse Events Best Practices," Orange County Regulatory Affairs Discussion Group (OCRA), Irvine, CA
Oct. 22, 2015	"Forging a New Global Inspection/Auditing Process: Improving Quality and Ensuring Safety and Effectiveness," Orange County Regulatory Affairs Discussion Group (OCRA) and San Diego Regulatory Affairs Network (SDRAN) Program, Carlsbad, California
June 3-4, 2015	"The Current Regulatory Landscape: Opportunities and Challenges," FDA-OCRA 18th Annual Educational Conference, Irvine, CA ○ *Session Organizer and Moderator: "Real World Reasons Why Proper Pharmacovigilance Matters"*
June 4-5, 2014	"Integrated Regulatory Pathways in a Global Market," 17th Annual FDA-OCRA Educational Conference, Irvine, California ○ *Session Organizer and Moderator: "Risk Management: Postmarketing Requirements and Strategies"*
Dec. 10, 2013	"Afternoon At The District," Orange County Regulatory Affairs Discussion Group (OCRA), Irvine, California
Sept. 30 – Oct. 2, 2013	2013 Regulatory Affairs Professionals Society (RAPS) Annual Conference: "The Regulatory Convergence," Boston, Massachusetts
June 6, 2013	"Skadden Seminar for Pharmaceutical, Biotechnology and Medical Device Companies: A Dialogue on Regulation, Litigation and Shareholder Activism," Costa Mesa, California
Nov. 1, 2012	"RAPS/FDA Case for Quality Forum," Irvine, California
April 24-25, 2012	The Food and Drug Law Institute's 55th Annual Conference, Washington, D.C.
Nov. 2, 2011	"How to Avoid the Escalation of Enforcement Activities," Orange County Regulatory Affairs Discussion Group (OCRA), Irvine, California
Oct. 19, 2011	"Corporate Compliance: Understanding the Current Enforcement Climate," Orange County Regulatory Affairs Discussion Group (OCRA) and San Diego Regulatory Affairs Network (SDRAN) Joint Meeting, San Diego, California
Sept. 26-27, 2011	The Food and Drug Law Institute's Advertising and Promotion Conference for the Pharmaceutical, Medical Device, Biologic and Veterinary Medicine Industries, Washington, D.C.
Feb. 8-10, 2011	Medical Design and Manufacturing (MD&M) West 2011 Conference, Anaheim, California
Oct. 7, 2010	Town Hall Meeting, FDA's Center for Devices and Radiological Health (CDRH), Irvine, California
Oct. 6, 2010	"Getting Your Product to Market in the New Regulatory Environment," Orange County Regulatory Affairs Discussion Group (OCRA) and San Diego Regulatory Affairs Network (SDRAN) Joint Meeting, San Diego, California
June 16-17, 2010	"The Business of Compliance," 13th Annual FDA-OCRA Educational Conference, Irvine, California ○ *Session Moderator: "Enforcement Activities of Significance"*
May 19, 2010	California Life Sciences Day at the State Capitol, Sacramento, California
April 28, 2010	"Risk Management for Regulated Industries," Orange County Regulatory Affairs Discussion Group (OCRA), Irvine, California
March 10, 2010	"Navigating CAPA: Smooth Sailing with Continuous Improvement," Orange County Regulatory Affairs Discussion Group (OCRA), Irvine, California
Feb. 8-10, 2010	"Marketing a Medical Device in the US" and "The Future is Now: Anticipating a New Era of FDA Enforcement, Parts I & II," MD&M West 2010 Conference, Anaheim, California
Jan. 26, 2010	"Regulatory Strategies for Biologics Development," San Diego Regulatory Affairs Network (SDRAN) Annual Meeting & Presentation, San Diego, California
Nov. 19, 2009	"Adoption Process of Novel Technologies: Challenges and Solutions," Drug Safety Executive Council (DSEC) Webinar

SELECTED CONTINUING EDUCATION (Continued)

Nov. 6, 2009	"Convergence, Creating BioSynergy," BioFlorida's 12th Annual Conference, Orlando, Florida
Oct. 21, 2009	"European Regulation on Advanced Therapies," The Weinberg Group, Webinar
Sept. 30, 2009	"ANDA vs. 505(b)(2) – When and Why?," The Weinberg Group, Webinar
Sept. 14-16, 2009	Regulatory Affairs Professionals Society (RAPS) Annual Conference & Exhibition, Philadelphia, Pennsylvania
Sept. 9, 2009	"FDA's New Strategy on Enforcement: The Growing Perils of Inadequate Compliance," The Weinberg Group, Webinar
June 9-10, 2009	"The Challenges of Ensuring Product Safety," 12th Annual FDA-OCRA Educational Conference, Irvine, California
May 27, 2009	"Global Lessons in Developing Biosimilars," The Weinberg Group, Webinar
April 15, 2009	"Pharmaceutical Development in Europe: Key Points to Consider," The Weinberg Group, Webinar
April 7-8, 2009	2009 Florida Medical Device Symposium, Florida Medical Manufacturer's Consortium, Inc., Tampa, Florida
Jan. 29, 2009	"Workshop on Accessing Government Funding for Bioscience Research," Southern California Biomedical Council, Westwood, California
Nov. 19, 2008	"Global Clinical Trials: An Overview and Update," Orange County Regulatory Affairs Discussion Group (OCRA) and San Diego Regulatory Affairs Network (SDRAN) Joint Meeting, Carlsbad, California
Sept. 19, 2008	10th Southern California Biomedical Council Investor Conference, Los Angeles, California
June 16, 2008	Israel Life Sciences Day at BIO 2008, La Jolla, California
June 11-12, 2008	"Regulatory Affairs: Expanding to Global Horizons," 11th Annual FDA-OCRA Educational Conference, Irvine, California
Feb. 8, 2008	"Striving for Regulatory Success in a Changing Environment," Hyman, Phelps & McNamara, PC, Medical Device Seminar, Newport Beach, California
June 11-12, 2007	"Celebrating 10 Years of Regulatory Affairs Education," 10th Annual FDA-OCRA Educational Conference, Irvine, California
Nov. 30 – Dec. 1, 2006	2006 Global Summit on AIDS and the Church: Race Against Time, Saddleback Church Campus, Lake Forest, California
Nov. 14-15, 2006	"Intersections: Converging Fields, Emerging Opportunities," BioFlorida Annual Conference, Gainesville, Florida
Aug. 13-18, 2006	XVI International AIDS Conference, Toronto, Canada
Nov. 29-30, 2005	HIV/AIDS Conference, Saddleback Church Campus, Lake Forest, California
June 4-5, 2003	"Understanding the Changing Landscape," 6th Annual FDA-OCRA Educational Conference, Irvine, California
March 12-13, 2001	"Opportunities for Drug Development and Discovery in Women's Health," Drug Information Association (DIA), Washington, D.C.
Oct. 25, 1999	"Annual Update on Women's Health Research: Discoveries and Implications," Ninth Annual Scientific Advisory Meeting, Society for the Advancement of Women's Health Research, Washington, D.C.
March 22-23, 1999	"Contracting with Site Management Organizations," Barnett International Conference Group, Philadelphia, Pennsylvania
June 25-29, 1995	"The Changing Regulatory Environment and Its Impact on Global Healthcare," Drug Information Association (DIA) 31st Annual Meeting, Orlando, Florida ○ *Session Chairperson: Current Research Targets in Biotechnology Including Therapeutics and Therapeutic Vaccines*
May 20-25, 1995	Ninth Biotechnology Industry Organization (BIO) International Biotechnology Meeting & Exhibition, San Francisco, California
Dec. 7-8, 1993	"In Vitro Diagnostics – A Regulatory Update," Regulatory Affairs Professionals Society (RAPS) 1993 Educational Programs, San Francisco, California

SELECTED CONTINUING EDUCATION (Continued)

July 11-15, 1993	"Global Drug Development: Focus on the Americas," Drug Information Association (DIA) 29th Annual Meeting, Chicago, Illinois
April 12-16, 1993	Association of Biotechnology Companies 7th International Biotechnology Meeting & Exhibition, Research Triangle Park, North Carolina
June 8-11, 1992	"Pharmaceutical Development: National and Transnational Dynamics," Drug Information Association (DIA), San Diego, California
Feb. 27, 1992	"Micro Planner X-Pert" Training, Amgen Corporate Information Technologies, Thousand Oaks, California
Circa 4th Qtr. 1991	"Preparing for an FDA-GCP Audit," Barnett International Seminar, prepared and presented for Amgen, Inc.
Jan. 10-14, 1990	"Clinical and Experimental Approaches to Dermal and Epidermal Repair: Normal & Chronic Wounds," 3rd International Symposium on Tissue Repair, Miami, Florida
May 18-20, 1988	"Project Management in the Pharmaceutical Industry," The Institute for Applied Pharmaceutical Sciences, Los Angeles, California
Jan. 16-17, 1986	"Introduction to Laboratory Techniques: Biochemical Separations," Cook College, Continuing Professional Education, Rutgers University, New Brunswick, New Jersey
Nov. 14-15, 1985	"Gene and Its Product," Cook College, Office of Short Courses and Professional Training, Rutgers University, New Brunswick, New Jersey
July 11, 1984	"Ophthalmic Toxicology," The Center for Professional Advancement, East Brunswick, New Jersey
June 15-19, 1981	Course: Breath Tests in Intoxication, Indiana University School of Medicine, Indianapolis, Indiana

SELECTED COMMUNITY AND CIVIC ACTIVITIES

2012	Charter Member, Rotary E-Club of One World
2006 – 2011	Rotary International, The Rotary Club of Westlake Village ○ *International Committee and Meals on Wheels Administrator, 2008* ○ *Program Chair, 2009 – 2010* ○ *Club Service Chair and Board of Directors, 2010 – 2011*
2002	Ageless for Life Radio Show, Health and Fitness Speaker and Consultant, Chicago, Illinois
2001 – 2002	Los Angeles World Affairs Council, International Circle
1983	Instructor, City/County Marijuana Education Program, Indianapolis, Indiana
1983	Senior Editor and Pharmacology Consultant, Health Alert Publishing Company, Indianapolis, Indiana
1982 – 1984	Invited Speaker on substance abuse, to a variety of parent, student, and professional groups
1982 – 1983	Volunteer Staff by Invitation, Fairbanks Hospital, specializing in the treatment of alcoholism and drug addiction, Indianapolis, Indiana